



COMMONWEALTH of VIRGINIA
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MEMORANDUM

TO: BRIAN MCCORMICK
Regulatory and Manual Section Manager
Department of Medical Assistance Services

FROM: ELIZABETH A. MCDONALD
Special Counsel to DMAS

DATE: May 13, 2008

SUBJECT: Emergency Regulations concerning MAC Reimbursement for Specialty Drugs

I have reviewed the attached emergency regulations that would create a specialty drug reimbursement methodology based upon the Wholesale Acquisition Cost (WAC).

Based on that review, it is this Office's view that the Director of the Department of Medical Assistance Services ("DMAS"), acting on behalf of the Board of Medical Assistance Services pursuant to Va. Code § 32.1-324, has the authority to promulgate these regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority.

The authority for this emergency action is found in Va. Code § 2.2-4011, which provides that an "emergency situation" is a "situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment..." The amendments to the regulations will enable the Director, in lieu of the Board of Medical Assistance Services, to comply with Item 302 JJ of the 2008 Appropriations Act which gives DMAS authority to create a specialty drug reimbursement methodology based upon the WAC.

Accordingly, with the prior approval of the Governor, these regulations will qualify for the “emergency” exemption from Article 2 requirements. Please be advised, however, that under Va. Code § 2.2-4011(A), the Department must state in writing the nature of and necessity for such emergency action, and this appears to have been accomplished in the “Agency Background Document.” In addition, the regulations shall be effective for no more than twelve months. As the Department intends to continue regulating the subject matter governed by this emergency regulation beyond 12 months, it will be necessary to replace these emergency regulations with regulations duly promulgated under Article 2 of the APA. A Notice of Intended Regulatory Action relating to the proposed replacement regulations must be filed with the Registrar within 60 days of the effective date of the emergency regulations (and it appears that this has been done). The proposed replacement regulations must be filed with the Registrar within 180 days after the effective date of the emergency regulations.

If you have any questions or need any additional information, please feel free to contact me at 786-3890.